UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,790	03/30/2001	Wei Shao	CL001204	3620

7590 08/26/2003

CELERA GENOMICS CORPORATION
45 West Gude Dr. C2-4#20
Rockville, MD 20850

EXAMINER
PRIEBE, SCOTT DAVID

ART UNIT	PAPER NUMBER
1632	13

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,790	SHAO ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 20, and 21, drawn to an isolated peptide of SEQ ID NO: 2, classified in class 530, subclass 350.

II. Claim 3, drawn to an antibody that binds the peptide of SEQ ID NO: 2, classified in class 530, subclass 387.9.

III. Claims 4, 5, 8, 9, 22, and 23, drawn to an isolated nucleic acid molecule of SEQ ID NO: 1 or 3, classified in class 536, subclass 23.5.

IV. Claim 6, drawn to a gene chip comprising a nucleic acid molecule of SEQ ID NO: 1 or 3, classified in class 435, subclass 6.

V. Claim 7, drawn to a transgenic animal comprising a nucleic acid molecule of SEQ ID NO: 1 or 3, classified in class 800, subclass 13.

VI. Claims 10 and 11, drawn to a recombinant method for producing the peptide of SEQ ID NO: 2, classified in class 435, subclass 69.1.

VII. Claims 12 and 13, drawn to a method for detecting the peptide of SEQ ID NO: 2 using a detection agent, classified in class 435, subclass 7.4.

VIII. Claims 14-16, drawn to a method for identifying an agent that binds or modulates the activity (kinase) of the peptide of SEQ ID NO: 2, classified in class 435, subclass 7.15.

IX. Claims 17 and 18, drawn to an pharmaceutical composition comprising an agent identified by invention VIII and method of treating a disease therewith, classified in class 514, subclass cannot be determined, no agents described by structure.

X. Claim 19, drawn to a method for identifying a modulator of expression of the peptide of SEQ ID NO: 2, classified in class 435, subclass 29.

The inventions are distinct, each from the other because of the following reasons:

Inventions VI and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the peptide of invention I could be isolated from cells or tissues that express the peptide naturally, i.e. non-recombinantly.

Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptide of invention I can be used in a method of making the antibodies of invention II.

Invention II and inventions VII, VIII or IX are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case not all of the antibodies of invention II would modulate peptide activity or would be useful in the treatment method of invention IX. Inventions VII, VIII and IX embrace agents or compounds that are not antibodies. Also, the antibody of invention II can be used to affinity purify the peptide of invention I.

Inventions IV or V and invention III are related as combinations and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination may encode the peptide of SEQ ID NO: 2, an allelic variant or ortholog of SEQ ID NO: 2, or a fragment of any of these. The subcombination has separate utility such as either a component of the gene chip or part of the transgenic animal or used in cultured cells for recombinant production of the peptide.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

1) Invention I is unrelated to inventions II-V, VII, IX and X. The isolated peptide is a structurally different compound from that of the antibody (II) or nucleic acid molecule (III-V), with a different mode of operation and function, and is not disclosed as being usable with these compounds. The isolated peptide is not used in the methods of inventions VII, IX, or X.

2) Invention II is unrelated to inventions III-VI and X. The antibody is a structurally and functionally different compound than the nucleic acid molecule, and is not disclosed as being usable with the nucleic acid molecule. The antibody is not used in the methods of invention VI or X.

3) Inventions III-V are unrelated to the methods of inventions VII-X, as they are not used in these methods.

4) Inventions VI-X are unrelated, as each is directed to a different method requiring different products and having different modes of operation and functions, i.e. different ultimate uses.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other group, and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Scott D. Priebe
Primary Examiner
Art Unit 1632